

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today
(1) was not written for publication in a law journal and
(2) is not binding precedent of the Board.

Paper No. 37

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KURT LEANDER, JAN GUNZINGER
and BORJE ROSEN

Appeal No. 1996-0682
Application 08/127,121¹

HEARD: September 16, 1999

Before METZ, JOHN D. SMITH and LIEBERMAN, Administrative
Patent Judges.

JOHN D. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the
final rejection of claims 25 through 35 and 37, the only

¹Application for patent filed September 27, 1993, which is
a continuation of Application No. 07/778,920 filed March 2,
1992, now abandoned.

Appeal No. 1996-0682
Application 08/127,121

claims in the application. As evident from representative
appealed claim

25 reproduced below, the subject matter on appeal is directed
to an acidic pharmaceutical cream preparation containing the
active ingredient, podophyllotoxin, and between 3 and 15
weight percent of fractionated coconut oil triglyceride.

25. A pharmaceutical cream preparation, consisting
essentially of:

an effective amount of podophyllotoxin for treating
psoriasis or condyloma acuminata, and between 3 and 15
weight percent of a medium chain length liquid
triglyceride which is a fractionated coconut oil;

wherein the cream preparation is prepared by
suspending the podophyllotoxin in the liquid triglyceride
to form a fatty phase, and then emulsifying the fatty
phase with an aqueous phase; and

wherein the pharmaceutical cream preparation
possesses a pH value of between 2 and 6.

Prior art references relied upon by the examiner as
evidence of obviousness are:

Evers 1980	4,235,889	Nov. 25,
Jacobsen et al. (Jacobsen) 1984	0,119,852	Sep. 26,
European Patent Application Leander et al. (Leander) 29, 1988	4,788,216	Nov.
Makino et al. (Makino) 1988	4,789,667	Dec. 6,

The appealed claims 25-35 and 37 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Leander, Makino, Evers and Jacobsen. We affirm.

As background, we note that appellants' claimed pharmaceutical cream composition is used for the treatment of psoriasis and condyloma acuminata (genital warts), and for this purpose the composition includes the active ingredient, podophyllotoxin. See the specification at page 1. While the use of this active ingredient for treatment of each of these diseases is known (specification, page 1, lines 20-27), appellants allege that the presence of a medium chain length liquid triglyceride, such as fractionated coconut oil,² in their podophyllotoxin composition unexpectedly results in a stable preparation that is effective and has few side effects when used to treat psoriasis and condyloma acuminata. See the specification at page 2, lines

² Fractionated coconut oil consists of a triglyceride of caprylic/capric acid (C₈ and C₁₀ acids). A commercially available form of fractionated coconut oil is sold under the trade name Miglyol. See the specification at page 2, lines 27-31.

1-7 and lines 24-31. To avoid unwanted side effects when treating psoriasis, appellants state that the concentration of podophyllotoxin should be kept low, and a preparation containing about 0.1 weight percent is preferred. See the specification at page 2, lines 8-15.

As evidence of obviousness of the claimed subject matter on appeal, the examiner relies on the combined disclosures of Leander, Makino, Evers, and Jacobsen. Appellants characterize Leander, the examiner's "primary reference," as disclosing a method of treating psoriasis using a podophyllotoxin cream composition, "but no specific pharmaceutical preparation is described." See the specification at page 1, lines 24-27. In fact, Leander describes a detailed clinical investigation using creams containing 0.1%, 0.25%, and 0.5% podophyllotoxin for treatment of 152 patients afflicted with psoriasis vulgaris which produced "statistically significant improvements" at all three dosage levels. See Leander at column 4, line 21 to column 5, line 8. Although the Leander reference does not specifically describe how the prior art podophyllotoxin creams were made or the specific ingredients included therein, the

reference indicates that as carrier materials for the cream, "[a]ll those materials can be used which are known to be useful in the preparation of pharmacolological preparations, provided they do not react unfavorably with the active compound or exert some unsuitable effect together therewith."

See column 2, lines

21-26. Thus, contrary to appellants' arguments in the brief at page 6, the above disclosure in Leander implies that the problem of providing a stable pharmaceutical cream preparation was a prior art concern. Further, Leander states that "[I]t is within the knowledge of one skilled in the art to prepare a suitable composition when the way of administration and other conditions of administration are known." See column 2, lines 21-38 of Leander.

In his answer at pages 6 and 8, the examiner contends that appellants' claimed fractionated coconut oil cream component "is well known in the art of pharmaceutical compounding" and has been used in cream formulations as "a standard carrier." Since appellants have raised no challenge

to these statements³ in their briefs, we accept them as being factual. In re Eskild,

387 F.2d 987, 989, 156 USPQ 208, 209-10 (CCPA 1968).

Based on the arguments in appellant's brief at page 6, we assume that Leander actually used a carrier other than fractionated coconut oil in the described prior art creams. (Appellants' assignee and co-appellant Kurt Leander have not favored this record by disclosing what specific ingredients or carrier components were utilized in the creams described in

³ The examiner's statements are supported by disclosures in U. S. Patent No. 5,104,656 issued to Seth et al.(Seth) on April 14, 1992 and U.S Patent No. 4,837,019 issued to Georgalas et al. (Georgalas) on June 6, 1989. See column 2, lines 39-42 and examples 1 and 2 of Seth which describes an ibuprofen-S cream utilizing 2 to 15 percent of fractionated coconut oil as the oily component of an oil-in-water emulsion used in a cream formulation, and the skin treatment cream composition of example 1 of Georgalas which utilizes a propylene glycol dicaprylate/dicaprate component referred to as Miglyol 840. See the examiner's discussion of these references in the answer at page 6. Also see U.S. Patent No. 4,150,141 issued to Berger on April 17, 1979 which describes a typical topical pharmaceutical cream dosage form for the treatment of scabies as including Miglyol 812(caprylic/capric triglyceride) as a component in the lipid phase of the cream. See column 3, lines 49-60 of Berger. A copy of this reference is attached to this decision. All the above cited prior art establishes that, as of appellants' filing date, fractionated coconut oil was a well-known non-reactive excipient for preparing creams in the pharmaceutical art.

the prior art Leander patent). However, we agree with the examiner that it would have been prima facie obvious to utilize the prior art "standard carrier," fractionated coconut oil, as a carrier material component for the podophyllotoxin creams described in the Leander patent, invited by Leander's statement that all useful prior art carrier materials may be utilized by one skilled in the art to prepare the prior art creams especially those which do not react unfavorably with the active compound or exert some unsuitable effect when combined with the active compound.

Moreover, notwithstanding appellants' arguments in the brief, we agree with the examiner that Makino constitutes additional evidence of the obviousness of successfully using fractionated coconut oil in a podophyllotoxin cream composition. In this regard, Makino teaches a cream preparation which may include, inter alia, podophyllotoxin as an active ingredient and may include the "normally used" fractionated coconut oil as an oil component for a body temperature soluble solid preparation. See Makino at column 9, line 44; column 11; lines 49-68. Thus, the examiner persuasively argues that it would have been obvious to a

person with ordinary skill in the art to utilize the fractionated coconut oil of Makino as a carrier for Leander's creams, because "Makino teaches that fractionated oil is a conventional excipient for body temperature-soluble solid preparations such as creams. . . . " See the answer at page 3. Contrary to appellants' arguments, the appealed "consisting essentially of" composition claims do not exclude the presence of Makino's required penetration enhancer component, because there is no evidence of record demonstrating that a penetration enhancer component would "materially affect the basic and novel characteristics" of appellants' composition. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976).

We recognize that the claimed cream preparation must possess a pH value of between 2 and 6. With respect to this claimed requirement, Jacobsen teaches a pharmaceutical preparation incorporating the claimed active ingredient (Jacobsen, page 2), which is preferably buffered to a pH in the range of 2.5 to 6 to 1) increase the efficacy of the composition and 2) improve the stability of the composition. See Jacobsen at page 4. We agree with the examiner that one

of ordinary skill in this art would have been led to buffer the Leander creams to a pH value as claimed, motivated by the desire and a reasonable expectation of enhancing the efficacy of the podophyllotoxin preparation. See the answer at page 4.

Evers discloses a pharmaceutical preparation for the treatment of psoriasis with a carrier comprising coconut oil and an emulsifier. See Evers at column 1, lines 15-17, 31-38.

(The examiner primarily cites Evers to teach the use of an antioxidant, a limitation that appears exclusively in independent claim 37, as a common component for preparations directed to the treatment of psoriasis which "prevent oxidative destruction" in the preparation. See the answer at pages 3 and 4 and Evers at column 4, lines 15-29.) In our view, one may reasonably imply from the relevant disclosures in Evers that a person of ordinary skill in this art would have had a reasonable expectation of success when using fractionated coconut oil (i.e., the C₈ and C₁₀ saturated acid glyceride components contained in coconut oil) in Leander's creams when treating patients suffering from psoriasis.

In light of the above, we agree with the examiner that the combined teachings of the references relied upon by the examiner are adequate to establish a prima facie case of obviousness for the subject matter defined by appealed claim 25. To the extent that appellants' specification asserts that the claimed composition is allegedly unexpectedly stable and has demonstrated an alleged "superior effect in comparison with placebo after only four weeks of treatment" of patients suffering from psoriasis (specification, page 2, lines 1-6 and page 4, lines 21-36), we note that appellants have offered no data with respect to these properties or effects for the claimed compositions or for the prior art creams described in Leander, the closest prior art. Accordingly, we find that the subject matter defined by appealed claim 25 would have been obvious within the meaning of 35 U.S.C. § 103, and we therefore affirm the rejection of this claim. Since appealed claims 26-30 and 37 fall with appealed claim 25, we necessarily also affirm the rejection of these claims.

Appellants ask for separate consideration for the subject matter defined by appealed claims 31-35 which relates to a cream preparation containing an effective amount of

Appeal No. 1996-0682
Application 08/127,121

podophyllotoxin for treating condyloma acuminata. Suffice it to say that since the effective amount of the active ingredient for the treatment of psoriasis is substantially the same as the effective amount of the active ingredient for treating genital warts (specification, page 2, lines 8-15 and lines 19-24), this claimed requirement which is directed to the intended use of the composition does not serve to differentiate the claimed composition from that of Leander. Again, see Leander at column 4, lines 27-29. Accordingly, we also affirm the rejection of appealed claims 31-35.

The decision of the examiner, accordingly, is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

)	
ANDREW H. METZ)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
JOHN D. SMITH)	
Administrative Patent Judge)	APPEALS AND

Appeal No. 1996-0682
Application 08/127,121

)	
)	INTERFERENCES
)	
PAUL LIEBERMAN)	
Administrative Patent Judge)	

JDS:hh

Appeal No. 1997-0682
Application No. 08/127,121

BIRCH, STEWART, KOLASCH & BIRCH
P.O. Box 747
Falls Church, VA 22040-0747